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(पहला पुनरीक्षण)

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — ELECTROMYOGRAPH-SPECIFICATION

(*First Revision*)

UDC 615.841 : 616.74 — 009·5-073·96

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BUREAU OF INDIAN STANDARDS
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October 1994 **Price Group** 4

Electromedical Equipment Sectional Committee, MHD 19

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard covers the requirements of electromyographs which display myoelectric/ bioelectric potentials from site/locations picked up by means of electrodes suitably applied to the body on cathode ray tube (including storage and memory) augmented by a sufficiently loud sound pattern as an auditory signal output or any other audio-visual means. The instrument is used for neuromuscular investigations. The standard lays down essential safety and performance requirements as well as methods of tests and the atmospheric conditions under which the electromyograph would work satisfactorily.

This Indian Standard was first published in 1978. This, first revision, incorporates the following modifications:

a) The requirements relating to built-in celiberater have been specified;

b) The requirements relating to input and input impedance, sweep speed, sweep mode and nerve stimulator have been modified;

c) Requirements for controls and connections have been thoroughly revised and updated; and

d) Particular requirements and tests for safety have been incorporated in addition to the existing reference to IS 13450 (Part 1) : 1994 'Medical electrical equipment — General requirements for safefy'.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — ELECTROMYOGRAPH — SPECIFICATION

(*First Revision*)

1 SCOPE

1.1 This standard covers the safety and performance requirements, and test methods for single and multichannel electromyographs.

2 REFERENCE

2.1 The Indian Standard IS 13450 (Part 1): 1994 'Medical electrical equipment — General requirements for safety' is a necessary adjunct to this standard.

3 TERMINOLOGY

3.1 Accuracy

The deviation of a result from the true value. It is usually expressed as a percentage.

3.2 Attenuator

Provision to reduce the input signal level (available at the input terminal) to the basic sensitivity of an amplifier (before being applied to the input of the amplifier).

3.3 Blocking Time

The time following transients at which the signals may again be displayed with acceptable fidelity.

3.4 CMR (Common Mode Rejection)

The ability of a differential amplifier to reject common mode signals. It is expressed as a ratio, namely:

$$\text{Common mode rejection ratio (CMRR)} = \frac{\text{Gain of the amplifier for differential mode signal}}{\text{Gain of the amplifier for common mode signal}}$$

3.5 Electromyograph (EMG)

An electromedical equipment used for displaying of the myoelectric/bioelectric potentials from site/locations picked up by means of electrodes (surface of needle), suitably applied to the patient, for neuromuscular investigations. The display will be a visual display on the cathode ray tube (including storage and memory) augmented by a sufficiently loud sound pattern as an auditory signal output, with a provision for permanent record either on a strip chart recorder or on a magnetic tape recorder or on photofilm or combinations.

3.5.1 *Single Channel Electromyograph*

Equipment for the display of myoelectric/bioelectric potentials from one site/location.

3.5.2 *Multichannel Electromyograph*

Equipment for the simultaneous display of myoelectric/bioelectric potentials from more than one site/location.

3.6 Distortion

The change in shape of a myoelectric/bioelectric potential waveform introduced by the EMG instrument.

3.6.1 *Linear Distortion*

A type of distortion resulting when the gain of EMG amplifier varies with the frequency of the sinusoidal signal for a constant amplitude sinusoidal input.

3.6.2 *Non-linear Distortion*

A type of distortion in which the output departs from the sinusoidal wave shape when the input is sinusoidal.

3.7 Frequency Response

A record of the sensitivity of the electromyograph *versus* the frequency of sinusoidal input in the specified range, keeping input amplitude constant.

3.8 Impedance

A measure of the opposition to flow of an alternating current in a circuit caused by the combination of resistance, capacitive reactance and inductive reactance. It is the ratio of the effective voltage to the effective current.

3.9 Input Signal

The signal injected into the electromyograph.

3.10 Input Terminal

The terminal or terminals for the input signal of an electromyograph.

3.11 Input Circuit

The part of the electronic circuit immediately adjacent to the input terminals.

3.12 Linearity

A measure of the non-linear distortion (see 3.6.2) in an electromyograph.

3.13 Noise

Unwanted signal introduced either from the electromyograph or from other non-biological sources.

3.14 Output

The conversion of an input *as* it appears in the form of a signal output in the electromyograph as visual and/or auditory and/or recording on the strip-chart or magnetic tape recorder and/ or photofilm or combinations.

3.15 Output Terminal

The terminals or terminal on an EMG to which any external device can be connected.

3.16 **Output Circuit**

That part of the electronic circuit immediately adjacent to the terminals described in **3.15.**

3.17 Sensitivity

The ratio of the amplitude of the output signal to that of the input signal expressed as microvolts per division.

3.18 Signal

The electromyographic waveform attributable to the electrical activity of the nerve/muscle.

3.19 Time Constant

The time required for the output obtained from a direct current step input to decay to 36·8 percent of its original magnitude.

3.20 Surface Electrode

Electrode fastended on a certain part of the body to detect myoelectric/bioelectric action potentials in combination with another electrode.

3.21 Ground Electrode

Reference point for differential amplifiers.

3.22 Needle Electrode

Concentric needle electrode is in the form of a needle, inside which an insulated platinum wire is inserted. Insulation is usually provided by polytetrafluoroethylene (PTFE) coating of the platinum wire.

NOTE — This electrode is normally employed for investigations of interior of muscles. The electrical activity may pertain to a single or a group of motor units or a set of muscle fibres.

4 SERVICE CONDITIONS

4.1 Electromyograph shall be capable of complying with the requirements of this specification over the full range of each of the following conditions, including any combination thereof:

a) Over the temperature range 10°C to 40°C inclusive.

NOTE — The electromyograph shall be capable of working in a temperature from 40°C to 50°C under dry heat conditions.

b) At altitudes from sea level to 3 000 metres above sea level.

c) At relative humidity up to 95 percent inclusive.

d) i) *For electromyograph operating from a normal* 240 *V, 50 Hz supply*

At any supply voltage within the range of 200 to 255 V inclusive and 48 to 52 Hz inclusive.

ii) *For battery operated electromyograph*

To the end point of the voltage limits specified by the manufacturer.

5 CONSTRUCTION AND GENERAL REQUIREMENTS

5.1 All the subsystems shall make use of solid state devices/integrated circuit chips.

5.2 The system shall be designed to work from supply mains and/or battery.

5.3 Electromyograph shall be calibrated at least once in 3 months for checking the accuracy in time and amplitude scales.

5.3.1 *Built-in Calibrator*

5.3.1.1 A built-in calibrator shall be provided to facilitate quick check-up of sensitivity calibration before the use of electromyograph.

5.3.1.2 The calibrator output shall be 100 Hz, 500 μV, and square wave pulse.

5.3.1.3 The output of the calibrator shall be connected through switch on the pre-amplifier unit, to the input to the pre-amplifier.

5.3.1.4 While calibrating the EMG unit, the sensitivity control shall be in 500 μV/cm position to get 1 cm display on cathode ray tube.

5.4 EMG Amplifier

5.4.1 The amplifier shall be capable of amplifying the myoelectric/bioelectric action potential signals from the patient which are displayed visually on the cathode-ray tube, or fed to recording and/or display devices. The amplifier shall be completely of solid state design. The amplifier shall meet the requirements **specified as given below.**

5.4.1.1 *Input*

The input stage shall incorporate a pre-amplifier-cum-impedance transfer stage. It shall be housed in a portable box. The DC low voltage power supply for this pre-amplifier unit shall be tapped from the main unit. It shall have its ON/OFF control. It shall provide high input impedance and low output impedance to drive a cable of 1 m length required to be used between the patient and the main unit having the operational controls.

5.4.1.2 *Input impedance*

The amplifier shall have effective input impedance higher than:

a) 100 megohm for different mode signal, and

b) 50 megohm for common mode signal.

5.4.1.3 *Basic sensitivity*

The basic sensitivity of the amplifier shall be such as to give on the CRT, 1 cm display for the input signal of 5 μV peak-to-peak amplitude.

The overall sensitivity of the amplifier shall be such as to give 1 cm display on CRT for an input signal of 5 μV to 25 mV peak-to-peak amplitude.

Overall sensitivity shall preferably be covered by calibrated attenuators in 1, 2 and 5 sequence.

The calibration voltage accuracy shall be better than ± 5 percent. In case, a separate fine sensitivity control is provided, the same shall have a calibrated position at which the calibration of the calibrated control holds good.

5.4.1.4 *Frequency response*

The amplifier shall have the frequency response over a frequency range of 1 Hz to 20 kHz (3 dB down) in the normal mode of operation.

The amplifier shall have the frequency response of 20 Hz to 10 kHz (3 dB down) in 'L.F. cut' mode of operation (for nerve conduction investigations).

5.4.1.5 *Blocking time*

The amplifier shall have the blocking time of the order of 100 ms.

5.4.1.6 *Noise*

The amplifier shall have noise level at shorted input not greater than 5 μV peak-to-peak amplitude at full frequency range as in 5.4.1.4.

5.4.1.7 *Common mode rejection ratio (CMRR)*

The unit shall have CMRR not less than 80 dB at 50 Hz.

5.4.1.8 *Output*

Nominal 1 V rms across 50 ohms and the output shall be short-circuit proof.

5.5 Time Base

5.5.1 *Sweep Speed*

The EMG shall have sweep speed of 0·5 ms/cm to 100 ms/cm preferably in 1, 2 and 3 sequence.

5.5.2 *Accuracy*

Accuracy shall be better than 3 percent.

5.5.3 *Sweep Mode*

The electromyograph sweep generator shall have the facilities to select:

a) EMG mode,
b) nerve-conduction velocity mode, and
c) external stimulus mode.

5.6 Display

5.6.1 ***Visual Display***

a) Display area 6 x IO divisions, *Min.* For 13 cm CRT, each division shall be 1 cm.

b) CRT phospher suitable for visual observation as well as photography.

5.6.2 *Auditory Display*

a) Audio amplifier, and
b) Loudspeaker.

5.6.2.1 *Audio amplifier*

a) The amplifier shall have frequency response of 10 Hz to 15 kHz (3 dB down);

b) The amplifier shall be suitably compensated for pulse response;

c) Signal input to the audio amplifier shall be controlled by the attenuator of the EMG amplifier;

d) Volume control for adjusting the sound level shall be provided; and

e) Audio amplifier shall be capable of delivering the maximum output power of 2 to 3 W to the loudspeaker.

5.7 Nerve Stimulator

5.7.1 Stimulus waveform shall be square wave and may be triggered either manually in the form of singal pulse or automatically at a given frequency.

5.7.2 ‘The stimulator shall have a selector switch for single, double or continuous stimulation pulses.

5.7.3 The stimulus frequency shall be variable as 1, 2, 3, 5, 10, 15 and 50 pulses/s.

5.7.4 The impulse amplitude shall be continuously variable from 0 to 300 V.

5.7.5 The stimulus pulse shall be 0·1 ms.

5.7.6 The stimulator output shall be isolated/floating from the ground.

5.7.7 The output impedance shall be $\leq$ 100 ohms.

5.8 **Latency Unit**

5.8.1 A latency unit shall be incorporated for direct measurement of latency.

5.8.2 ‘It shall produce two vertical marking lines or two intense spots.

5.8.3 One line or spot marker shall indicate the moment of stimulation.

5.8.4 The second line or spot marker shall be shifted horizontally to coincide with the front edge of the response signal.

5.8.5 The time interval between these two lines or spot markers, that is, the latency, shall be read on a counter or a dial.

5.8.6 The time interval shall range from 0 to 100 ms.

5.8.7 The accuracy shall be better than ± 5 percent of the reading indicated by the controls.

6 CONTROLS AND CONNECTIONS

6.1 An electromyograph shall have the following controls.

6.1.1 *General*

a) Power ON/OFF switch, and

b) Lamp or indicator to indicate presence of power.

6.1.2 *Amplifier Unit*

Each amplifier shall have:

a) *Input selector*

EMG input either grounded or connected to the patient.

Where the pre-amplifier is a separate unit, this switch shall be incorporated in the pre-amplifier.

b) *Sensitivity control*

One for each channel, covering the entire range of sensitivity. In case a separate fine sensitivity control is provided, the same shall have a calibrated position at which the calibration of the calibrated control holds good.

c) *Frequency range selection*

A switch for selection of band-width on each channel for:

i) upper frequency cut off, and

ii) low frequency cut off (time constant).

6.1.3 *Time Base*

a) **Mode** selector shall have the facilities for:

i) EMG mode,

ii) nerve-conduction velocity mode, and

iii) external stimulus mode.

b) Sweep speed selector to select time base speeds.

6.1.4 *Stimulator*

a) ON/OFF switch for the stimulator;

b) Stimulus rate selector to select 1, 2, 3, 5, 10, 25 and 50 pulses/s;

c) *Stimulus height*

i) O-300 V, and

ii) Continuously variable control to cover the above ranges.

d) *Stimulus duration*

0·1 ms.

6.1.5 *Loudspeaker*

a) Volume control, and

b) A jack shall be provided for external loudspeaker connection so as to enable the internal speaker to be disconnected as and when required, and external speaker to be connected. The impedance of the speaker shall be indicated on the panel just below the jack.

6.1.6 *Oscilloscope*

a) Intensity;

b) Focus;

c) Position control, vertical; and

d) Position control, horizontal.

6.1.7 *Sockets and Connectors*

a) Power input socket (fixed mains cord preferred);

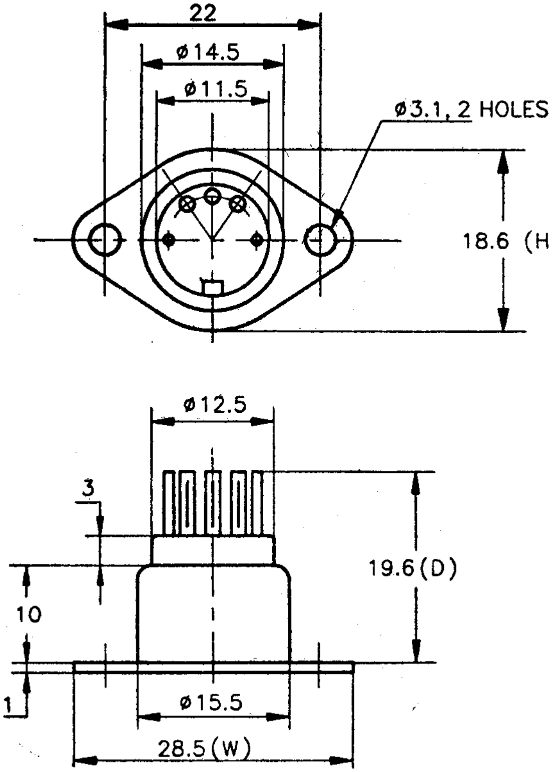
b) Puse;

c) Earthing socket/metal binding terminal;

d) External loudspeaker; and

e) *Tape recorder socket*

One 5-pin socket (see Fig. 1) wired according to standard tape recorder connections;



All dimensions in millimetres.

FIG. 1 5-PIN SOCKET

Signal input socket (for pre-amplifier)

One 5-pin (Din type) (5-way 240") socket (see Fig. 1) for each channel, wired as below:

i) Pin No. 1 & 2 — Differential input to the pre-amplifier;

ii) Pin No. 3 – Connected to ground;

iii) Pin No. 4 & 5 — No connection;

iv) Signal input socket (for pre-amplifier) — Two, 2 mm banana sockets, 1 cm apart for surface electrodes, parallel wired with Pin No, 1 and '2 above; and

v) Ground socket (for pre-amplifier) — One, 4 mm banana socket and one 2 mm banana socket connected in parallel for patient ground.

g) *Signal input connector:*

For needle electrode:

i) Pin No. 1 — Inner core of the concentric electrode, near nerve electrode for unipolar electrodes or electrode No. 1 in bifilar and/or multi-electrodes.

ii) Pin No. 2 — Cannula of the concentric electrode, remote electrode for unipolar electrodes or electrode No. 2 in bifilar and/or multi-electrodes.

iii) Pin No. 3 & 4 — Electrode cable shield. In case of separate shielded leads (as used for bifilar and multi-electrodes). Pin No. 3 is used for the shield of lead to electrode 'No. 1 and Pin No. 4 for the shield to electrode No. 2.

iv) Pin No. 5 — Ground.

For surface electrode : Two, 2 mm banana pins;

h) *EMG amplifier output* — BNC socket, one for each channel;

j) *External trigger input* — BNC socket;

k) *Stimulus output socket* — 3 pins (see Fig. 2) and two, 4 mm banana sockets, one in red and the other in black colour.

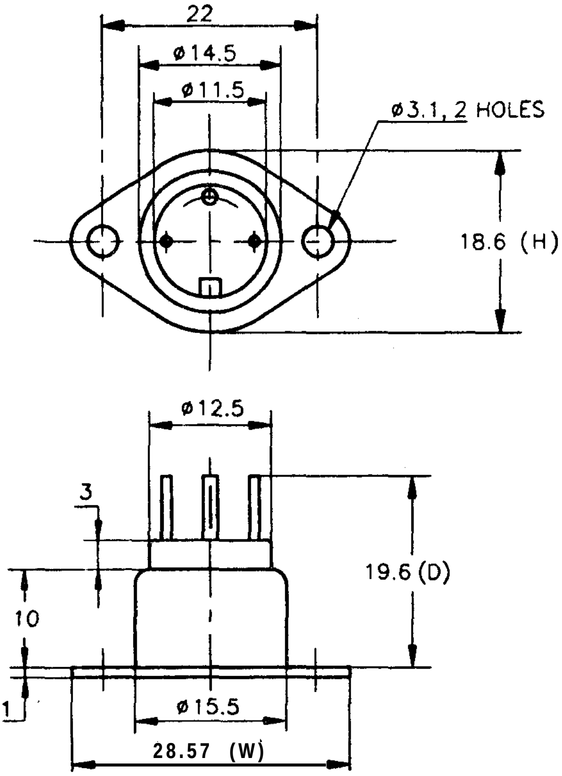
Pin No. 1 and 2 are the floating output connections while Pin No. 3 is connected to the ground.

6.1.8 *Latency Unit*

a) ON/OFF switch for latency unit,

b) Potentiometer for shifting second line or spot marker, and

c) Calibrated scale or readout for direct reading of latency.



All dimensions in millimetres.

FIG. 2 3-PIN SOCKET

7 SAFETY REQUIREMENTS AND TESTS

7.1 Power source for electromyograph shall have 3 pin socket of 5 A capacity. The ground pin of the 5 A socket shall be connected to specially prepared ground point in the hospital/ clinic building. This ground point shall be checked for correct grounding before the installation of electromyograph at the hospital.

7.1.1 Fuse wire of appropriate current rating shall be used in the power source for electromyograph.

7.1.2 Only one instrument shall be connected on one power plug. Number of instruments on one power plug may cause performance degradation of electromyograph. Such connections cause ground loop formation and at times electrical hazards due to faulty ground connection on one of the instruments. LIVE pin and NEUTRAL pin shall be strictly followed.

7.1.3 Power source to operate EMG-unit shall be derived using a mains-isolation transformer. The stimulus voltage shall be generated using a patient-isolation transformer.

7.1.3.1 Relevant provisions of IS 13450 (Part 1) : 1993 shall apply.

8 PERFORMANCE REQUIREMENTS AND TESTS

8.1 EMG Amplifier

Basic setting for all measurements, unless otherwise stated, shall be as follows:

a) The sensitivity control of EMG amplifier shall be in its most sensitive position,

b; The amplifier shall be in its full frequency range,

c) The time base shall be in the internal or free running position,

d) The output shall be read on the oscilloscope of the unit,

e) The input signal shall be sinusoidal and of frequency 1 kHz, and

f) The EMG unit shall be connected to the power source and earthed according to the instructions of the manufacturer.

Mains power connection should follow the conventional way of indicating live, neutral and ground pins.

8.1.1 *Basic and Overall Sensitivity*

8.1.1.1 Connect the EMG amplifier according to Fig. 3A.

8.1.1.2 Vary the input signal so that the trace on the CRT screen is 10 mm in height.

8.1.1.3 Read the value of the input signal from the signal generator. This reading gives the basic sensitivity of the amplifier.

8.1.1.4 Feed an input signal of 5 μV peak-to-peak and obtain a deflection of 10 mm on the CRT (use fine control, if provided).

8.1.1.5 At different positions of the attenuator, check the deflection on the CRT while at the same time adjusting the output of the signal generator to correspond with the attenuator step.

The maximum deviation in the CRT deflection shall be not more than ± 5 percent in accordance with 5.4.1.3.

8.1.2 *Frequency Response*

Connect the amplifier as shown in Fig. 3A.

8.1.2.1 Adjust the height of the trace to a value, say four divisions, by varying the input.

8.1.2.2 Keeping the amplitude of the input signal constant, vary the frequency of the signal generator through the entire frequency range of the myograph.

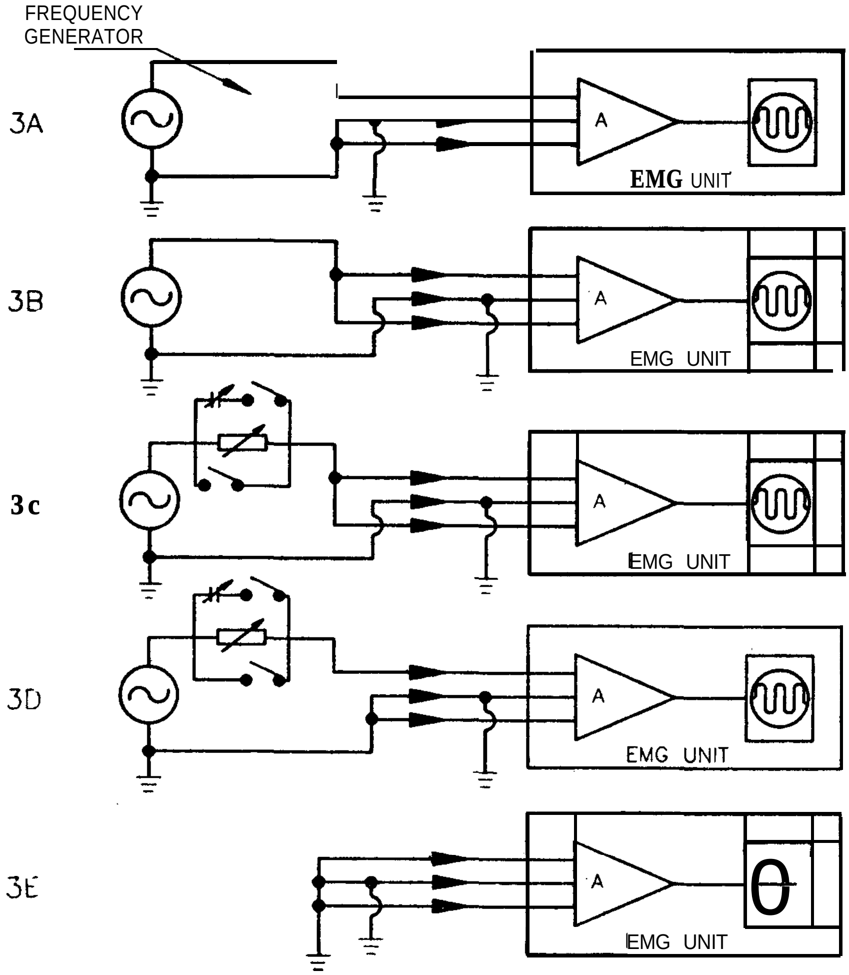


FIG. 3 CONNECTIONS OF EMG UNIT FOR PERFORMANCE TESTS

8.1.2.3 Plot the response curve of height *versus* frequency.

8.1.2.4 The 3 dB drops shall be as specified in 5.4.1.4.

8.1.2.5 Check the 3 dB drops at the reduced frequency bandwidth position of the amplifier.

8.1.3 *Measurement of Common Mode Rejection Ratio*

8.1.3.1 Connect the unit as shown in Fig. 3A. Feed a signal of 50 Hz and obtain a trace of say, four divisions on the CRT screen.

8.1.3.2 Connect the myograph as shown in Fig. 3B.

8.1.3.3 Increase the input signal to obtain the same value as in 8.1.3.1.

8.1.3.4 The ratio of the common mode input and the difference mode input gives the common mode rejection ratio.

8.1.3.5 Repeat the above procedure at signal frequencies of 1 kHz and 5 kHz.

8.1.4 *Input Impedance*

8.1.4.1 Common mode input impedance

a) Connect the amplifier as shown in Fig. 3C.

b) Feed a 1 kHz signal to get an amplitude of four divisions on the screen.

c) Introduce a variable resistance in series with the input signal and adjust until the height of the trace drops by 10 percent.

d) The input impedance is obtained by multiplying the series resistance by 9.

e) Feed a signal of say, 5 kHz and introduce a shunting capacitance. Vary the input capacitance until the height of the trace is 10 percent of four divisions. The shunt capacitance of the amplifier is 1/9 of that of the known shunt capacitor.

8.1.4.2 *Differential mode input impedance*

a) Connect the amplifier as shown in Fig. 3D.

b) Feed a 1 kHz signal to obtain a height of four divisions on the CRT.

c) Introduce a variable resistance in series with the input signal and adjust until the height of the trace drops by 10 percent-

d) Calculate the input impedance by multiplying the series resistance value by 9.

8.1.5 *Noise Level*

8.1.5.1 Connect the input to ground as shown in Fig. 3E.

8.1.5.2 Observe the trace on the CRT.

8.1.5.3 Peak of the noise pulses shall be less than 5 μV peak-to-peak.

8.1.6 *H.F. Cut and L.F. Cut*

8.1.6.1 Connect the (sine wave) signal generator to Pin No. 1 and connect Pin No. 2 of input socket to earth.

8.1.6.2 Connect ground of the signal generator to Pin No. 5 of the input socket.

8.1.6.3 EMG amplifier is in normal mode of operation.

8.1.6.4 Feed the 5 kHz signal of sufficient height to get four divisions of trace on CRT.

8.1.6.5 Turn the control to H.F. cut mode of operation.

8.1.6.6 Vary the input signal frequency and note the height of the trace on CRT at 2 kHz. It shall be 10 percent of that of the normal mode of operation.

8.1.6.7 Turn the control to L.F. cut mode of operation.

8.1.6.8 Vary the input signal frequency and note the height of the trace on CRT at 20 Hz. It shall be 10 percent of that of the normal mode of operation.

8.2 Time Base

8.2.1 Connect the time marker in place of the signal generator as shown in Fig. 3A.

8.2.2 Connect the ground of the time mark generator to the input socket ground.

8.2.3 Trigger the time base externally by synchronizing pulses from the time mark generator.

8.2.4 Obeserve the trace for 1 : 1 coincidence of the time markers with the marking on the graticule or scale.

8.2.5 Repeat the procedure for the entire range of sweep speeds.

8.3 Stimulator

8.3.1 Stimulus frequency shall be measured in accordance with 8.3.1.1 and 8.3.1.2.

8.3.1.1 Connect the stimulus output to the cathode-ray oscilloscope.

8.3.1.2 Vary the stimulus frequency and observe the stable display on the oscilloscope which shall give the measurement of the stimulus frequency.

8.3.2 Stimulus amplitude shall be measured in accordance with 8.3.2.1 and 8.3.2.2.

8.3.2.1 Connect the stimulus output to the oscilloscope.

8.3.2.2 Vary the stimulus amplitude/height control and observe the stable display on the oscilloscope which shall give the measurement of the stimulus amplitude/height.

8.3.3 Stimulus duration shall be measured in accordance with 8.3.2.1 and 8.3.2.2.

8.3.3.1 Connect the stimulus output to the oscilloscope.

8.3.3.2 Vary the stimulus duration control and observe the stable display on the oscilloscope which shall give the measurement of the stimulus duration.

8.3.4 Output impedance shall be measured in accordance with 8.3.4.1 to 8.3.4.5.

8.3.4.1 Connect the stimulus output to the oscilloscope.

8.3.4.2 Set the impulse amplitude/height such that the display of four divisions of heignt on CRT is made available.

8.3.4.3 Shunt the output terminals of the stimulus output socket by the variable resistance.

8.3.4.4 Vary the resistance till the display height drops down to half of that specified in 8.3.4.2, that is, two divisions.

8.3.4.5 The resistance value gives the effective output impedance.

8.3.5 Check or measure the stimulator output floating from the ground.

8.4 Latency Unit

8.4.1 Connect the time marker in place of the signal generator as shown in Fig. 3A.

8.4.2 Trigger the time base with the marker generator.

8.4.3 Observe the second line for 1 : 1 coincidence with the time marker.

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This Indian Standard has been developed from Doc : No. MHD 19 (2377).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Printed at Printwell Printers, Aligarh, India